H.R. 7667 would reauthorize the collection and spending of user fees by the Food and Drug Administration (FDA) for activities related to the approval and marketing of prescription drugs and medical devices. The bill also would amend the Federal Food, Drug, and Cosmetic Act in part to change processes and procedures for regulating, manufacturing, and marketing certain prescription drugs, medical devices, and other medical products.

Table 1

Estimated Budgetary Effects of H.R. 7667, the Food and Drug Amendments of 2022 Act, as Posted on the Website of the Clerk of the House on June 3, 2022

https://docs.house.gov/billsthisweek/20220606/BILLS-117hr7667-SUSv1.pdf

By Fiscal Year, Millions of Dollars

		2022	2023	2024	2025	2026	2027	2028	2029	2030	2031	2032	2022-2027	2022-2032
Increases or Decreases (-) in Direct Spending														
Sec. 601	Increasing transparency in generic drug applications													
	Budget Authority	0	-12	-29	-35	-41	-43	-48	-44	-51	-54	-57	-160	-414
	Outlays	0	-12	-29	-35	-41	-43	-48	-44	-51	-54	-57	-160	-414
Sec. 602	Enhancing access to affordable medicines													
	Budget Authority	0	-1	-3	-3	-4	-4	-5	-5	-6	-6	-6	-15	-43
	Outlays	0	-1	-3	-3	-4	-4	-5	-5	-6	-6	-6	-15	-43
Sec. 711	Reauthorization of provision related to exclusivity of certain drugs containing single enantiomers													
	Budget Authority	0	0	0	0	0	0	0	1	4	6	6	0	17
	Outlays	0	0	0	0	0	0	0	1	4	6	6	0	17
Sec. 902	Medicaid Improvement Fund													
	Budget Authority	0	0	0	450	0	0	0	0	0	0	0	450	450
	Outlays	0	0	0	450	0	0	0	0	0	0	0	450	450
Total Changes in Direct Spending														
	Budget Authority	**0**	**-13**	**-32**	**412**	**-45**	**-47**	**-53**	**-48**	**-53**	**-54**	**-57**	**275**	**10**
	Outlays	**0**	**-13**	**-32**	**412**	**-45**	**-47**	**-53**	**-48**	**-53**	**-54**	**-57**	**275**	**10**
Increases or Decreases (-) in Revenues														
Sec. 601	Increasing transparency in generic drug applications	0	0	9	13	14	15	15	15	16	17	18	51	132
	On-budget revenues	*0*	*0*	*6*	*9*	*10*	*11*	*11*	*11*	*12*	*13*	*13*	*36*	*96*
	Off-budget revenues	*0*	*0*	*3*	*4*	*4*	*4*	*4*	*4*	*4*	*4*	*5*	*15*	*36*
Sec. 602	Enhancing access to affordable medicines	0	0	1	1	1	1	1	1	1	1	1	4	9
	On-budget revenues	*0*	*0*	*1*	*1*	*1*	*1*	*1*	*1*	*1*	*1*	*1*	*4*	*9*
	Off-budget revenues	*0*	*0*	*	*	*	*	*	*	*	*	*	*	*
Sec. 711	Reauthorization of provision related to exclusivity of certain drugs containing single enantiomers	0	0	0	0	0	0	0	*	-1	-1	-1	0	-3
	On-budget revenues	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*	*-1*	*-1*	*-1*	*0*	*-3*
	Off-budget revenues	*0*	*0*	*0*	*0*	*0*	*0*	*0*	*	*	*	*	*	*
Total Changes in Revenues		**0**	**0**	**10**	**14**	**15**	**16**	**16**	**16**	**16**	**17**	**18**	**55**	**138**
	On-budget revenues	*0*	*0*	*7*	*10*	*11*	*12*	*12*	*12*	*12*	*13*	*13*	*40*	*102*
	Off-budget revenues	*0*	*0*	*3*	*4*	*4*	*4*	*4*	*4*	*4*	*4*	*5*	*15*	*36*
Net Decrease (-) in the Deficit From Changes in Direct Spending and Revenues														
Effect on the Deficit		**0**	**-13**	**-42**	**398**	**-60**	**-63**	**-69**	**-64**	**-69**	**-71**	**-75**	**220**	**-128**
	On-budget deficit	*0*	*-13*	*-39*	*402*	*-56*	*-59*	*-65*	*-60*	*-65*	*-67*	*-70*	*235*	*-92*
	Off-budget deficit	*0*	*0*	*-3*	*-4*	*-4*	*-4*	*-4*	*-4*	*-4*	*-4*	*-5*	*-15*	*-36*

* = between -$500,000 and $500,000.

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Section 601 would authorize the Food and Drug Administration (FDA) to disclose qualitative and quantitative information on the inactive ingredients of a reference brand drug in response to a request in a controlled correspondence for a generic drug. Section 602 would allow the FDA to approve the marketing application for a generic drug whose label differs from that of the reference brand product when the reference product's label changes within 90 days of the date on which the generic application would otherwise have been eligible for approval. The sponsor of the generic drug would be required to update that drug's label within 60 days of approval. Based on conversations with stakeholders, CBO expects that both provisions would accelerate the availability of lower-priced generic drugs that manufacturers would choose to market earlier than current law allows. Therefore, CBO anticipates, the provisions would reduce the average prices for those drugs that are paid by federal health programs that purchase or provide health insurance that covers drugs.

Section 711 of the bill would reauthorize through 2027 a provision that allows sponsors of drugs developed from a particular type of molecule called an enantiomer to elect five-year data exclusivity under certain circumstances; that period is two years longer than allowed under current law. (Five-year data exclusivity begins when a drug is approved by the FDA; during that time, the agency does not accept applications for marketing approval for generic versions of the drug). Based on historical data, CBO expects that extending market exclusivity for prescription drugs would, in some cases, delay the entry of lower-priced generic versions of those drugs.

Section 902 of the bill would appropriate $450 million for the Medicaid Improvement Fund in fiscal year 2025. Other provisions in H.R. 7667 would have insignificant effects on direct spending and revenues. The areas of significant uncertainty for this table include CBO's estimates of sales, market effects, and timing of introductions of new pharmaceutical products.

H.R. 7667 would impose private-sector mandates as defined in the Unfunded Mandates Reform Act (UMRA). The bill would impose fees on drug, biological product, and device developers and manufacturers, amend the application and approval process for certain products, expand notification duties, and ban electrical stimulation devices, among other mandates. Those mandates are included in Sections 103, 203, 303, 403, 721, 801, 803, 804, 808, and 811. CBO estimates the cost of the mandates would exceed the private-sector threshold established in UMRA ($184 million in 2022, adjusted annually for inflation). The bill would not impose any intergovernmental mandates.

Table 2

CBO's Estimate of the Statutory Pay-As-You-Go Effects of H.R. 7667, the Food and Drug Amendments of 2022 Act, as Posted on the Website of the Clerk of the House on June 3, 2022

https://docs.house.gov/billsthisweek/20220606/BILLS-117hr7667-SUSv1.pdf

	By Fiscal Year, Millions of Dollars												
	2022	2023	2024	2025	2026	2027	2028	2029	2030	2031	2032	2022-2027	2022-2032
	Net Decrease (-) in the On-Budget Deficit												
Pay-As-You-Go Effect	0	-13	-39	402	-56	-59	-65	-60	-65	-67	-70	235	-92
Memorandum:													
Changes in On-Budget Outlays	0	-13	-32	412	-45	-47	-53	-48	-53	-54	-57	275	10
Changes in On-Budget Revenues	0	0	7	10	11	12	12	12	12	13	13	40	102

The Statutory Pay-As-You-Go Act of 2010 establishes budget-reporting and enforcement procedures for legislation affecting direct spending or revenues. The net changes in outlays and revenues that are subject to those procedures are shown here. In addition, CBO estimates H.R. 7667 would increase off-budget revenues by $36 million over the 2022-2032 period.

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